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10/583,093	06/15/2006	Andreas Nandy	MERCK-3179	1555

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EXAMINER	
ROONEY, NORA MAUREEN	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,093	NANDY ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/15/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-17 are pending.

2. Applicant's election with traverse of Group II, claims 10-12, in the reply filed on 06/24/2008 is acknowledged. The traversal is on the ground(s) that

> "The requirement for restriction is respectfully traversed insofar as the Office Action has not demonstrated that an undue searching burden would be required to examine all groups and certainly not to examine at least more than one of the groups (for example, Groups II-III, which are *generally* directed to the molecules of the present invention and method(s) for the production thereof and/or use thereof). "If search and examination of an entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct invention." (Emphasis added.) See, M.P.E.P. ~803.
>
> Regarding Group III, claim 13, which is directed to a process of using the product of elected Group II, reference is made to the decisions in In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995), and In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996). The Commissioner's comments thereon in 1184 TMOG 86, March 26, 1996, indicate that, where product and process claims in the same application have been restricted and the elected product claim has been found allowable, withdrawn process claims including the limitations of the allowed product claim will be rejoined into the application and fully examined in that same application. It is respectfully submitted that the process claims herein should be rejoined and fully examined at such time as the product claim is found allowable.
>
> The requirement for election of species is traversed insofar as the Office Action has not demonstrated that it would constitute undue burden to examine more than one DNA sequence(s) which encode the claimed Lol p 4 polypeptide(s). To this end, Applicants cordially invite the Examiner to review the disclosure contained in the paragraph bridging pages 9 and 10 of the present specification and the disclosure contained in the sequence listing page."

This is not found persuasive because the Examiner has demonstrated that an undue searching burden would be required to examine all groups, given that the Groups are directed to independent and distinct inventions because (a) the inventions have acquired a separate status in the art in view of their different classification; (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter; (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries); (d) the prior art applicable to one invention would not

likely be applicable to another invention; and (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant's argument regarding the decisions in In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995) and In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996) are also unpersuasive. As detailed on page 7 of the restriction requirement mailed on 03/31/2008:

"The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01."

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-9 and 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/24/2008.

4. Applicant's IDS document filed on 06/15/2006 is acknowledged. However, the references were crossed out as none of the references were found in the case, so none were considered.

Claim Objections

5. Claims 10-12 are objected to because of the following informalities: Claims 10-12 are dependent upon non-elected base claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: a composition comprising a polypeptide encoded SEQ ID NO 1 or SEQ ID NO: 3, does not reasonably provide enablement for: a polypeptide according to Claim 10 **as medicament**; and **a pharmaceutical composition** comprising at least one polypeptide according to Claim 11 and optionally further active ingredients and/or adjuvants for the diagnosis and/or treatment of allergies in the triggering of which group 4 allergens from the *Poaceae are* involved of claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

At issue is whether or not the claimed composition would function as a medicament and/or pharmaceutical composition. The art of allergen immunotherapy as taught by Tarzi et al. (PTO-892; Reference U) teaches that whole allergen immunotherapy is unpredictable due to the retention of B-ell epitopes within the allergen which confers a risk of IgE-mediated potentially life-threatening systemic reactions (In particular, paragraph spanning pages 617-618, whole document) In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, absence of

working examples providing evidence which is reasonably predictive that the claimed pharmaceutical compositions are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,759,234 (PTO-892; Reference A).

U.S. Patent 6,759,234 teaches Lol p 4 for use as a medicament; and a pharmaceutical composition comprising Lol p 4 and adjuvant for the diagnosis and/or treatment of allergies. (In particular, column 6, line 43; column 12, line 42 to column 15, line 54; claims 1-20, whole document).

The recitation of "which is encoded by a DNA sequence according to Claim 1 (A DNA molecule encoding an allergen having the properties of corresponding to a nucleotide sequence selected from one of the sequences in accordance with SEQ ID NO 1 and 3)" is inherent in the reference Lol p IV protein.

It is noted that the instant claims are drawn to a product, not to a method. Therefore the intended use of "for use as a medicament" in claim 11 and "pharmaceutical composition" and "for the diagnosis and /or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved" in claim 12 do not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

Since the office does not have a laboratory to test the reference Lol p IV protein, it is applicant's burden to show that the reference Lol p IV protein is not encoded by SEQ ID NO:1 or SEQ ID NO:3 as recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

10. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Bose et al. (PTO-892; Reference W).

Bose et al. teaches isolated and purified Lol p 4. (In particular, page 580, 'Rye grass allergen LolpIV' section, whole document).

The recitation of "which is encoded by a DNA sequence according to Claim 1 (A DNA molecule encoding an allergen having the properties of corresponding to a nucleotide sequence selected from one of the sequences in accordance with SEQ ID NO 1 and 3)" is inherent in the reference Lol p IV protein.

It is noted that the instant claims are drawn to a product, not to a method. It is also noted that they pharmaceutical composition does not require any ingredients other than Lol p 4. Therefore, the intended use of "for use as a medicament" in claim 11 and "pharmaceutical composition" and "for the diagnosis and /or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved" in claim 12 do not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

Since the office does not have a laboratory to test the reference Lol p IV protein, it is applicant's burden to show that the reference Lol p IV protein is not encoded by SEQ ID NO:1 or SEQ ID NO:3 as recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

11. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Zhou et al. (PTO-892; Reference V).

Zhou et al. teaches Lol p 4 for use as a medicament; and a pharmaceutical composition comprising Lol p 4 and adjuvant (alum). (In particular, page 344, 'Preparation of allergen Lol pIV' section, whole document).

The recitation of "which is encoded by a DNA sequence according to Claim 1 (A DNA molecule encoding an allergen having the properties of corresponding to a nucleotide sequence selected from one of the sequences in accordance with SEQ ID NO 1 and 3)" is inherent in the reference Lol p IV protein.

It is noted that the instant claims are drawn to a product, not to a method. Therefore the intended use of "for use as a medicament" in claim 11 and "pharmaceutical composition" and "for the diagnosis and /or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved" in claim 12 do not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

Since the office does not have a laboratory to test the reference Lol p IV protein, it is applicant's burden to show that the reference Lol p IV protein is not encoded by SEQ ID NO:1 or SEQ ID NO:3 as recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

12. Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. WO 96/07428 (PTO-892; Reference N).

WO 96/07428 teaches Lol p 4 for use as a medicament; and a pharmaceutical composition comprising Lol p 4 and adjuvant for the diagnosis and/or treatment of allergies. (In particular, page 8, line 12; page 16, line 5 to page 19, line 25; claims 1-43, whole document).

The recitation of "which is encoded by a DNA sequence according to Claim 1 (A DNA molecule encoding an allergen having the properties of corresponding to a nucleotide sequence selected from one of the sequences in accordance with SEQ ID NO 1 and 3)" is inherent in the reference Lol p IV protein.

It is noted that the instant claims are drawn to a product, not to a method. Therefore the intended use of "for use as a medicament" in claim 11 and "pharmaceutical composition" and "for the diagnosis and /or treatment of allergies in the triggering of which group 4 allergens from the Poaceae are involved" in claim 12 do not carry patentable weight per se. The claims read on the active or essential ingredients of the composition.

Since the office does not have a laboratory to test the reference Lol p IV protein, it is applicant's burden to show that the reference Lol p IV protein is not encoded by SEQ ID NO:1 or SEQ ID NO:3 as recited in the claim. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

The reference teachings anticipate the claimed invention.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by

telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 24, 2008

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

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